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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,396	07/27/2001	Gregory M. Fahy	CENTMED.020A	7764

7590 12/31/2002
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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/31/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,396

Applicant(s)

Fahy

Examiner

Sandra Saucier

Art Unit

1651

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

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DETAILED ACTION

Claims 1-9 are pending. Claims 1-7 are considered on the merits. Claims 8 and 9 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 8 and 9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 8.

Upon determination of an allowable composition, claims to the use of that composition may be rejoined, if they present no issues of new matter or indefiniteness or enablement.

Specification

Please fill in the blanks on page 3, line 18, page 4, l. 30,

Tables 2 and 3 are not decipherable. For example, what is Veg, D(1)F, Acetol? Please see Merck Index [U], where acetol is a name open to various interpretations.

Where is the support in the text of the specification for the full name of these abbreviations?

Please carefully interpret all of the symbols in all of the tables and point to the place in the text where they are defined.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 4, 5, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites "further comprises ...". However, no components of the cryoprotectant are in claim 2. Should the claim read, "comprising...", or depend from claim 3.

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Likewise claim 6 recites "further comprises...". See remarks above concerning claim 4.

Claim 5 recites "is 80%" without stipulating upon what basis the % is calculated, for example, wt/wt, wt/vol or some other basis. Please point to the specification where this is discussed in order to avoid a new matter rejection upon amendment of the claim.

Claim 7 recites "where said non-penetrating components total 1.2 to 1.5 times isotonic."

This recitation does not make sense. First, "isotonic" is not a concentration and is not understood. Further, "isotonic" appears to be a relative word. Isotonic with what? Also, classification of compounds into penetrating or permeant and non-penetrating or impermeants depend on the purported subject. There are also differences in the literature concerning the penetrating abilities of the same substance towards the same subject. See US 6,194,137 [A], col. 6, line 41 where glucose is said to be an "impermeant chemical" and US 5,800,978 [B], col. 15, l. 34 where glucose is said to be a "permeable" compound. Further, penetrating and non-penetrating appear to be relative terms, not mutually exclusive ones. See US 2002/0451156 [C], col. 2, section 0010, for a discussion by one of skill in the art concerning the terms, permeable and non-permeable. In the present application, if one molecule of a compound penetrates the cell membrane, is this compound to be termed a "penetrating" one? In the absence of a definition, the limitations of penetrating vs. non-penetrating and isotonic are not interpretable, and to the extent that these limitations appear, the claims containing them have not been examined for art related purposes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 1-106826 [L] or Williams *et al.* [V].

The claims are directed to a solution to be used in the treatment of cell, tissue or organ with cryoprotectants comprising:

- 1) mannitol,
- 2) lactose,
- 3) vitrifiable concentrations of cryoprotectant.

JP 1-106826 disclose a composition used for the preservation of red cells comprising: mannitol and lactose with other sugars and sugar alcohols. See abstract.

Williams *et al.* disclose a solution comprising 5% mannitol and 1% lactose Table II.

Any liquid or solution is vitrifiable including pure water. Vitrification depends on the concentration of solutes and the rate of cooling as well as pressure. For, example, if one cools pure water quickly enough, it will vitrify at atmospheric pressure. See Ren *et al.* [W], Introduction, for a discussion. Also, mannitol and lactose are known to have cryoprotectant effects in the art, see US 5,879,875 [D]. Thus, this claim encompasses a solution containing only mannitol and lactose in any concentration since neither pressure nor cooling rate are specified.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,879,875 [D].

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The claims are directed to a solution to be used in the treatment of cell, tissue or organ with cryoprotectants comprising:

- 1) mannitol,
- 2) lactose,
- 3) vitrifiable concentrations of cryoprotectant.

US 5,879,875 disclose a composition for the preservation of living tissues comprising: a mixture of a first neutral solute preferably selected from raffinose, trehalose, sucrose, lactose (col. 2, l. 66) and a second neutral solute preferably selected from TMAO, betaine....mannitol, inositol (col. 3, l. 4). A cryoprotectant may be added (col. 7, l. 53).

Claims 3, 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,879,875 [D] as applied to claims 1, 2 and 7 above, and further in view of US 6,395,467 [E].

US 6,395,467 discloses a cryoprotectant comprising DMSO, formamide and ethylene glycol, see abstract. Other additions to the cryoprotectant composition may be polyvinyl alcohol or a copolymer with vinyl acetate at 1-25 mole percent (col. 9, l. 55).

The addition of the cryoprotectant disclosed in '467 to the solution disclosed in '875 would have been obvious because the addition of a cryoprotectant to the solution of '875 is specifically suggested (col. 7, l. 53). Any cryoprotectant known in the art may be incorporated.

Claim 6 appears to be free of the art.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00PM Monday, Tuesday and 8:30 AM to noon on Wednesday.

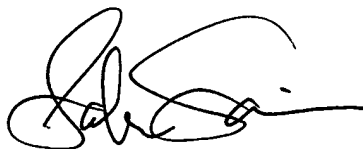
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number

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of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier
Primary Examiner
Art Unit 1651
December 27, 2002